No. 43252-8 II

COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON

PROTECT THE PENINSULA'S FUTURE, CLALLAM COUNTY CITIZENS FOR SAFE DRINKING WATER, and ELOISE KAILIN

Appellants,

v.

CITY OF PORT ANGELES and CITY OF FORKS

Respondents/Cross-Appellants,

ERRATUM TO ANSWER OF RESPONDENTS/CROSS-APPELLANTS CITY OF PORT ANGELES AND CITY OF FORKS TO AMICUS BRIEF OF OWOC! AND WASW

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ORIGINAL

ERRATUM

Respondents/Cross-Appellants City of Port Angeles and City of Forks ("Cities") filed and served their Answer Of Respondents/Cross-Appellants City Of Port Angeles And City Of Forks To Amicus Brief Of OWOD! And WASW (the "Answer") on December 21, 2012.

The Cities' Answer inadvertently failed to include the following four appendices, which were referenced in the Cities' Answer:

1. **Appendix A**: United Stated Food and Drug Administration ("FDA") Memorandum of Understanding 225-79-2001, as printed from the FDA website at: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm.
2. **Appendix B:** 21 U.S.C. §360bbb-1.
3. **Appendix C**: 21 U.S.C. §360bbb-2.
4. **Appendix D**: 21 C.F.R. Part 3, §3.1 through §3.10

Those appendices are attached to this Erratum for the convenience of the Court.

RESPECTFULLY SUBMITTED this 26th day of December, 2012.

FOSTER PEPPER PLLC

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Attorneys for Respondents

WILLIAM E. BLOOR, PORT ANGELES CITY ATTORNEY

William E. Bloor, WSBA #4084
Attorney for Respondent City of Port Angeles

William "Rod" Fleck, WSBA #23962
Attorney for Respondent City of Forks

DECLARATION OF SERVICE

Helen M. Stubbert declares:

I am a legal assistant to Roger A. Pearce. I am now, and at all times hereinafter mentioned was, a resident of the State of Washington, over the age of 18 years, and have personal knowledge of the facts in this declaration.

On December 26, 2012, I caused to be delivered in the manner indicated below a true and correct copy of the foregoing Erratum to Answer of Respondents/Cross-Appellants City of Port Angeles and City of Forks to Amicus Brief of OWOC! and WASW to the following:

Gerald Steel, PE
Attorney at Law
7303 Young Rd. N.W.
Olympia WA 98502
By email and U.S. Mail

I declare under penalty of perjury under the laws of the State of Washington, that the foregoing is true and correct.

Executed this 26th day of December, 2012, at Seattle, Washington.

Helen M. Stubbert

APPENDIX A

United Stated Food and Drug Administration ("FDA") Memorandum of Understanding 225-7-2001, as printed from the FDA website at: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116216.htm.

About FDA

MOU 225-79-2001

Memorandum of Understanding

Between
The Environmental Protection Agency

and

The Food and Drug Administration

I. Purpose:

This Memorandum of Understanding establishes an agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) with regard to the control of direct and indirect additives to and substances in drinking water.

EPA and FDA agree:

A. That contamination of drinking water from the use and application of direct and indirect additives and other substances poses a potential public health problem;

B. That the scope of the additives problem in terms of the health significance of these contaminants in drinking water is not fully known;

C. That the possibility of overlapping jurisdiction between EPA and FDA with respect to control of drinking water additives has been the subject of Congressional as well as public concern;

D. That the authority to control the use and application of direct and indirect additives to and substances in drinking water should be vested in a single regulatory agency to avoid duplicative and inconsistent regulation;

E. That EPA has been mandated by Congress under the Safe Drinking Water Act (SDWA), as amended, to assure that the public is provided with safe drinking water;

F. That EPA has been mandated by Congress under the Toxic Substances Control Act (TSCA) to protect against unreasonable risks to health and the environment from toxic substances by requiring, inter alia, testing and necessary restrictions on the use, manufacture, processing, distribution, and disposal of chemical substances and mixtures;

G. That EPA has been mandated by Congress under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to assure, inter alia, that when used properly, pesticides will perform their intended function without causing unreasonable adverse effects on the environment; and,

H. That FDA has been mandated by Congress under the Federal Food, Drug, and Cosmetic Act

(FFDCA), as amended, to protect the public from, inter alia, the adulteration of food by food additives and poisonous and deleterious substances.

It is the intent of the parties that:

A. EPA will have responsibility for direct and indirect additives to and other substances in drinking water under the SDWA, TSCA, and FIFRA; and,

B. FDA will have responsibility for water, and substances in water, used in food and for food processing and responsibility for bottled drinking water under the FFDCA.

II. Background:

A. FDA Legal Authority

"Food" means articles used for food or drink for man or other animals and components of such articles. (FFDCA Section 201(f)). Under Section 402, inter alia, a food may not contain any added poisonous or deleterious substance that may render it injurious to health, or be prepared, packed or handled under unsanitary conditions. Tolerances may be set, under Section 406, limiting the quantity of any substance which is required for the production of food or cannot be avoided in food. FDA has the authority under Section 409 to issue food additive regulations approving, with or without conditions, or denying the use of a "food additive." That term is defined in Section 201(s) to include any substance the intended use of which results or may reasonable be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, if such substance is not generally recognized as safe.

In the past, FDA has considered drinking water to be a food under Section 201(f). However, both parties have determined that the passage of the SDWA in 1974 implicitly repealed FDA's authority under the FFDCA over water used for drinking water purposes. Under the express provisions of Section 410 of the FFDCA, FDA retains authority over bottled drinking water. Furthermore, all water used in food remains a food and subject to the provisions of the FFDCA. Water used for food processing is subject to applicable provisions of FFDCA. Moreover, all substances in water used in food are added substances subject to the provisions of the FFDCA, but no substances added to a public drinking water system before the water enters a food processing establishment will be considered a food additive.

B. EPA Legal Authority

The SDWA grants EPA the authority to control contaminants in drinking water which may have any adverse effect on the public health, through the establishment of maximum contaminant levels (MCLs) or treatment techniques, under Section 1412, which are applicable to owners and operators of public water systems. The expressed intent of the Act was to give EPA exclusive control over the safety of public water supplies. Public water systems may also be required by regulation to conduct monitoring for unregulated contaminants under Section 1445 and to issue public notification of such levels under Section 1414(c).

EPA's direct authority to control additives to drinking water apart from the existence of maximum contaminant levels or treatment techniques is limited to its emergency powers under Section 1431. However, Section 1442(b) of the Act authorizes EPA to "collect and make available information pertaining to research, investigations, and demonstrations with respect to providing a dependably safe supply of drinking water together with appropriate recommendations therewith."

TSCA gives EPA authority to regulate chemical substances, mixtures and under some circumstances, articles containing such substances or mixtures. Section 4 permits EPA to require testing of a chemical substance or mixture based on possible unreasonable risk of injury to health

or the environment, or on significant or substantial human or environmental exposure while Section 8 enables EPA to require submission of data showing substantial risk of injury to health or the environment, existing health and safety studies, and other data. For new chemical substances, and significant new uses of existing chemical substances, Section 5 requires manufacturers to provide EPA with pre-manufacturing notice. Under Section 6 the manufacture, processing, distribution, use, and disposal of a chemical substance or mixture determined to be harmful may be restricted or banned. Although Section 3(2)(B) of TSCA excludes from the definition of "chemical substance" food and food additives as defined under FFDCA, the implicit repeal by the SDWA of FDA's authority over drinking water enables EPA to regulate direct and indirect additives to drinking water as chemical substances and mixtures under TSCA.

The FIFRA requires EPA to set restrictions on the use of pesticides to assure that when used properly, they will not cause unreasonable adverse effects on the environment. EPA may require, inter alia labeling which specifies how, when, and where a pesticide may be legally used. In addition, EPA has, under Section 409 of the FFDCA, required FIFRA registrants at times to obtain a food additive tolerance before using a pesticide in or around a drinking water source. Such tolerances establish further restrictions on the use of a pesticide which are enforceable against the water supplier as well as the registrant of the pesticide.

III. Terms of Agreement:

A. EPA's responsibilities are as follows:

1. To establish appropriate regulations, and to take appropriate measures, under the SDWA and/or TSCA, and FIFRA, to control direct additives to drinking water (which encompass any substances purposely added to the water), and indirect additives (which encompass any substance which might leach from paints, coatings or other materials as an incidental result of drinking water contact), and other substances.

2. To establish appropriate regulations under the SDWA to limit the concentrations of pesticides in drinking water; the limitations on concentrations and types of pesticides in water are presently set by EPA through tolerances under Section 409 of the FFDCA.

3. To continue to provide technical assistance in the form of informal advisory opinions on drinking water additives under Section 1442(b) of the SDWA.

4. To conduct and require research and monitoring and the submission of data relative to the problem of direct and indirect additives in drinking water in order to accumulate data concerning the health risks posed by the presence of these contaminants in drinking water.

B. FDA's responsibilities are as follows:

1. To take appropriate regulatory action under the authority of the FFDCA to control bottled drinking water and water, and substances in water, used in food and for food processing.

2. To provide assistance to EPA to facilitate the transition of responsibilities, including:

a) To review existing FDA approvals in order to identify their applicability to additives in drinking water.

b) To provide a mutually agreed upon level of assistance in conducting literature searches related to toxicological decision making.

c) To provide a senior toxicologist to help EPA devise new procedures and protocols to be used in

formulating advice on direct and indirect additives to drinking water.

IV. Duration of Agreement:

This Memorandum of Understanding shall continue in effect unless modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice to the other.

This Memorandum of Understanding will become effective on the date of the last signature.

Approved and Accepted for the Environmental Protection Agency

Signed by: Douglas P. Costle
Administrator
Environmental Protection Agency

Date: June 12, 1979

Approved and Accepted for the Food and Drug Administration

Signed by: Donald Kennedy
Administrator
Food and Drug Administration

Date: June 22, 1979

Page Last Updated: 04/30/2009
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

APPENDIX B

21 U.S.C. §360bbb-1.

C

Effective:|See Notes|

United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter V. Drugs and Devices
Part E. General Provisions Relating to Drugs and Devices
→→ § 360bbb-1. Dispute resolution

If, regarding an obligation concerning drugs or devices under this chapter or section 262 of Title 42, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the chapter involved, including a regulation promulgated under such chapter, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 355(n) of this title or an advisory committee described in section 360e(g)(2)(B) of this title. Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after November 21, 1997.

CREDIT(S)

(June 25, 1938, c. 675, § 562, as added Nov. 21, 1997, Pub.L. 105-115, Title IV, § 404, 111 Stat. 2368.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1997 Acts. House Conference Report No. 105-399, see 1997 U.S. Code Cong. and Adm. News, p. 2881.

Effective and Applicability Provisions

1997 Acts. Amendments by Pub.L. 105-115, the Food and Drug Administration Modernization Act of 1997, effective 90 days after November 21, 1997, except as otherwise provided, see section 501 of Pub.L. 105-115, set out as a note under 21 U.S.C.A. § 321.

RESEARCH REFERENCES

Encyclopedias

Am. Jur. 2d Drugs and Controlled Substances § 109, Expanded Access to Unapproved Therapies or Diagnostics.

(June 25, 1938, c. 675, § 563, as added Nov. 21, 1997, Pub.L. 105-115, Title IV, § 416, 111 Stat. 2378.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1997 Acts. House Conference Report No. 105-399, see 1997 U.S. Code Cong. and Adm. News, p. 2881.

Effective and Applicability Provisions

1997 Acts. Amendments by Pub.L. 105-115, the Food and Drug Administration Modernization Act of 1997, effective 90 days after November 21, 1997, except as otherwise provided, see section 501 of Pub.L. 105-115, set out as a note under 21 U.S.C.A. § 321.

RESEARCH REFERENCES

Encyclopedias

Am. Jur. 2d Drugs and Controlled Substances § 109, Expanded Access to Unapproved Therapies or Diagnostics.

21 U.S.C.A. § **360bbb**-2, 21 USCA § **360bbb**-2

Current through P.L. 112-197 approved 11-27-12

END OF DOCUMENT

APPENDIX C

21 U.S.C. §360bbb-2.

C

Effective:[See Notes]

United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)
Chapter 9. Federal Food, Drug, and Cosmetic Act (Refs & Annos)
Subchapter V. Drugs and Devices
Part E. General Provisions Relating to Drugs and Devices
→→ § 360bbb-2. Classification of products

(a) Request

A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 353(g) of this title or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) Statement

Not later than 60 days after the receipt of the request described in subsection (a) of this section, the Secretary shall determine the classification of the product under subsection (a) of this section, or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) Inaction of secretary

If the Secretary does not provide the statement within the 60-day period described in subsection (b) of this section, the recommendation made by the person under subsection (a) of this section shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

CREDIT(S)

(June 25, 1938, c. 675, § 563, as added Nov. 21, 1997, Pub.L. 105-115, Title IV, § 416, 111 Stat. 2378.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1997 Acts. House Conference Report No. 105-399, see 1997 U.S. Code Cong. and Adm. News, p. 2881.

Effective and Applicability Provisions

1997 Acts. Amendments by Pub.L. 105-115, the Food and Drug Administration Modernization Act of 1997, effective 90 days after November 21, 1997, except as otherwise provided, see section 501 of Pub.L. 105-115, set out as a note under 21 U.S.C.A. § 321.

RESEARCH REFERENCES

Encyclopedias

Am. Jur. 2d Drugs and Controlled Substances § 109, Expanded Access to Unapproved Therapies or Diagnostics.

21 U.S.C.A. § 360bbb-2, 21 USCA § 360bbb-2

Current through P.L. 112-207 (excluding P.L. 112-199, 112-202, 112-203, and 112-206) approved 12-7-12

END OF DOCUMENT

APPENDIX D

21 C.F.R. Part 3, §3.1 through §3.10

C

Effective:[See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101–629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological. This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device.

[68 FR 37077, June 23, 2003]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.1, 21 CFR § 3.1

Current through December 6, 2012; 77 FR 72762

END OF DOCUMENT

C

Effective: November 23, 2005

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.2 Definitions.

For the purpose of this part:

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b) Agency component means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.

(c) Applicant means any person who submits or plans to submit an application to the Food and Drug Administration for premarket review. For purposes of this section, the terms "sponsor" and "applicant" have the same meaning.

(d) Biological product has the meaning given the term in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(e) Combination product includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

(f) Device has the meaning given the term in section 201(h) of the act.

(g) Drug has the meaning given the term in section 201(g)(1) of the act.

(h) FDA means Food and Drug Administration.

(i) Letter of designation means the written notice issued by the product jurisdiction officer specifying the agency component with primary jurisdiction for a combination product.

(j) Letter of request means an applicant's written submission to the product jurisdiction officer seeking the designation of the agency component with primary jurisdiction.

(k) Mode of action is the means by which a product achieves an intended therapeutic effect or action. For purposes of this definition, "therapeutic" action or effect includes any effect or action of the combination product intended to diagnose, cure, mitigate, treat, or prevent disease, or affect the structure or any function of the body. When making assignments of combination products under this part, the agency will consider three types of mode of action: The actions provided by a biological product, a device, and a drug. Because combination products are comprised of more than one type of regulated article (biological product, device, or drug), and each constituent part contributes a biological product, device, or drug mode of action, combination products will typically have more than one identifiable mode of action.

(1) A constituent part has a biological product mode of action if it acts by means of a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the prevention, treatment, or cure of a disease or condition of human beings, as described in section 351(i) of the Public Health Service Act.

(2) A constituent part has a device mode of action if it meets the definition of device contained in section 201(h)(1) to (h)(3) of the act, it does not have a biological product mode of action, and it does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and is not dependent upon being metabolized for the achievement of its primary intended purposes.

(3) A constituent part has a drug mode of action if it meets the definition of drug contained in section 201(g)(1) of the act and it does not have a biological product or device mode of action.

(l) Premarket review includes the examination of data and information in an application for premarket review described in sections 505, 510(k), 513(f), 515, or 520(g) or 520(l) of the act or section 351 of the Public Health Service Act of data and information contained in any investigational new drug (IND) application, investigational device exemption (IDE), new drug application (NDA), biologics license application, device premarket notification, device reclassification petition, and premarket approval application (PMA).

(m) Primary mode of action is the single mode of action of a combination product that provides the most important therapeutic action of the combination product. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(n) Product means any article that contains any drug as defined in section 201(g)(1) of the act; any device as defined in section 201(h) of the act; or any biologic as defined in section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)).

(o) Product jurisdiction officer is the person or persons responsible for designating the component of

FDA with primary jurisdiction for the premarket review and regulation of a combination product or any product requiring a jurisdictional designation under this part.

(p) Sponsor means "applicant" (see § 3.2(c)).

[64 FR 398, Jan. 5, 1999; 64 FR 26657, May 17, 1999; 64 FR 56447, Oct. 20, 1999; 68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.2, 21 CFR § 3.2

Current through December 6, 2012; 77 FR 72762

END OF DOCUMENT

C

Effective:[See Text Amendments]

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ **§ 3.3 Scope.**

This section applies to:

(a) Any combination product, or

(b) Any product where the agency component with primary jurisdiction is unclear or in dispute.

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.3, 21 CFR § 3.3

Current through December 6, 2012; 77 FR 72762

END OF DOCUMENT

C

Effective: November 23, 2005

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.4 Designated agency component.

(a) To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product. Where the primary mode of action is that of:

(1) A drug (other than a biological product), the agency component charged with premarket review of drugs shall have primary jurisdiction;

(2) A device, the agency component charged with premarket review of devices shall have primary jurisdiction;

(3) A biological product, the agency component charged with premarket review of biological products shall have primary jurisdiction.

(b) In some situations, it is not possible to determine, with reasonable certainty, which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product. In such a case, the agency will assign the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product.

(c) The designation of one agency component as having primary jurisdiction for the premarket review and regulation of a combination product does not preclude consultations by that component with other agency components or, in appropriate cases, the requirement by FDA of separate applications.

[70 FR 49861, Aug. 25, 2005]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.4, 21 CFR § 3.4

Current through December 6, 2012; 77 FR 72762

END OF DOCUMENT

C

Effective:|See Text Amendments|

Code of Federal Regulations Currentness
Title 21. Food and Drugs
Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.5 Procedures for identifying the designated agency component.

(a)(1) The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research have entered into agreements clarifying product jurisdictional issues. These guidance documents are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are entitled "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health;" "Intercenter Agreement Between the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research;" "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research." The availability of any amendments to these intercenter agreements will be announced by Federal Register no- tice.

(2) These guidance documents describe the allocation of responsibility for categories of products or specific products. These intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public.

(3) The sponsor of a premarket application or required investigational filing for a combination or other product covered by these guidance documents may contact the designated agency component identified in the intercenter agreement before submitting an application of premarket review or to confirm coverage and to discuss the application process.

(b) For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application for premarket review should follow the procedures set forth in § 3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.5, 21 CFR § 3.5

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Chapter I. Food and Drug Administration, Department of Health and Human Services (Refs & Annos)
Subchapter A. General
Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.7 Request for designation.

(a) Who should file: the sponsor of:

(1) Any combination product the sponsor believes is not covered by an intercenter agreement; or

(2) Any product where the agency component with primary jurisdiction is unclear or in dispute.

(b) When to file: a sponsor should file a request for designation before filing any application for premarket review, whether an application for marketing approval or a required investigational notice. Sponsors are encouraged to file a request for designation as soon as there is sufficient information for the agency to make a determination.

(c) What to file: an original and two copies of the request for designation must be filed. The request for designation must not exceed 15 pages, including attachments, and must set forth:

(1) The identity of the sponsor, including company name and address, establishment registration number, company contact person and telephone number.

(2) A description of the product, including:

(i) Classification, name of the product and all component products, if applicable;

(ii) Common, generic, or usual name of the product and all component products;

(iii) Proprietary name of the product;

(iv) Identification of any component of the product that already has received premarket approval, is marketed as not being subject to premarket approval, or has received an investigational exemption, the identity of the sponsors, and the status of any discussions or agreements between the sponsors regarding the use of this product as a component of a new combination product.

(v) Chemical, physical, or biological composition;

(vi) Status and brief reports of the results of developmental work, including animal testing;

(vii) Description of the manufacturing processes, including the sources of all compon- ents;

(viii) Proposed use or indications;

(ix) Description of all known modes of action,

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Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ **§ 3.6 Product jurisdiction officer.**

The Office of Combination Products Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993–0002, 301–796–8930, e-mail: combination@fda.gov, is the designated product jurisdiction officer.

[68 FR 37077, June 23, 2003; 71 FR 16033, March 30, 2006; 75 FR 13678, March 23, 2010]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.6, 21 CFR § 3.6

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the sponsor's identification of the single mode of action that provides the most important therapeutic action of the product, and the basis for that determination.

(x) Schedule and duration of use;

(xi) Dose and route of administration of drug or biologic;

(xii) Description of related products, including the regulatory status of those related products; and

(xiii) Any other relevant information.

(3) The sponsor's recommendation as to which agency component should have primary jurisdiction based on the mode of action that provides the most important therapeutic action of the combination product. If the sponsor cannot determine with reasonable certainty which mode of action provides the most important therapeutic action of the combination product, the sponsor's recommendation must be based on the assignment algorithm set forth in § 3.4(b) and an assessment of the assignment of other combination products the sponsor wishes FDA to consider during the assignment of its combination product.

(d) Where to file: all communications pursuant to this subpart shall be addressed to the attention of the product jurisdiction officer. Such a request, in its mailing cover should be plainly marked "Request for Designation. Concurrent submissions of electronic copies of Requests for Designation may be addressed to combination@fda.gov."

[68 FR 37077, June 23, 2003; 70 FR 49861, Aug. 25, 2005]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.7, 21 CFR § 3.7

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Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ § 3.8 Letter of designation.

(a) Each request for designation will be reviewed for completeness within 5 working days of receipt. Any request for designation determined to be incomplete will be returned to the applicant with a request for the missing information. The sponsor of an accepted request for designation will be notified of the filing date.

(b) Within 60 days of the filing date of a request for designation, the product jurisdiction officer will issue a letter of designation to the sponsor, with copies to the centers, specifying the agency component designated to have primary jurisdiction for the premarket review and regulation of the product at issue, and any consulting agency components. The product jurisdiction officer may request a meeting with the sponsor during the review period to discuss the request for designation. If the product jurisdiction officer has not issued a letter of designation within 60 days of the filing date of a request for designation, the sponsor's recommendation of the center with primary jurisdiction, in accordance with § 3.7(c)(3), shall become the designated agency component.

(c) Request for reconsideration by sponsor: If the sponsor disagrees with the designation, it may request the product jurisdiction officer to reconsider the decision by filing, within 15 days of receipt of the letter of designation, a written request for reconsideration not exceeding 5 pages. No new information may be included in a request for reconsideration. The product jurisdiction officer shall review and act on the request in writing within 15 days of its receipt.

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.8, 21 CFR § 3.8

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Subpart A. Assignment of Agency Component for Review of Premarket Applications
→ **§ 3.9 Effect of letter of designa- tion.**

(a) The letter of designation constitutes an agency determination that is subject to change only as provided in paragraph (b) of this section.

(b) The product jurisdiction officer may change the designated agency component with the written consent of the sponsor, or without its consent to protect the public health or for other compelling reasons. A sponsor shall be given 30 days written notice of any proposed nonconsensual change in designated agency component. The sponsor may request an additional 30 days to submit written objections, not to exceed 15 pages, to the proposed change, and shall be granted, upon request, a timely meeting with the product jurisdiction officer and appropriate center officials. Within 30 days of receipt of the sponsor's written objections, the product jurisdiction officer shall issue to the sponsor, with copies to appropriate center officials, a written determination setting forth a statement of reasons for the proposed change in designated agency component. A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

[68 FR 37077, June 23, 2003]

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.9, 21 CFR § 3.9

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Part 3. Product Jurisdiction (Refs & Annos)
Subpart A. Assignment of Agency Component for Review of Premarket Applications
§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

SOURCE: 56 FR 58755, Nov. 21, 1991; 62 FR 51512, Oct. 1, 1997; 63 FR 26697, May 13, 1998; 64 FR 398, Jan. 5, 1999; 70 FR 49861, Aug. 25, 2005, unless otherwise noted.

AUTHORITY: 21 U.S.C. 321, 351, 353, 355, 360, 360c – 360f, 360h – 360j, 360gg – 360ss, **360bbb – 2**, 371(a), 379e, 381, 394; 42 U.S.C. 216, 262, 264.

21 C. F. R. § 3.10, 21 CFR § 3.10

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